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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,328	02/09/2000	Michael D. Macklin	7011-0032	3700

22428 7590 08/10/2004

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/501,328

**Applicant(s)**

MACKLIN ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17May2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8,10,11,13-16,18,19,21-30,32,33,35-42,44,45 and 47-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 50-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7,8,10,11,15,16,18,19,21,23,25-30,32,33,37-42,44,45 and 47-49 is/are rejected.
- 7) ☒ Claim(s) 13,14,22,24,35 and 36 is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5-17-04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-8,10,11,13-16,18,19,21-30,32,33,35-42,44,45 and 47-55.

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 17May2004, is acknowledged. Claims 7, 8, 16, 25, 30, and 42 have been amended.
2. Claim 1-8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 are pending. Claims 1-6 and 50-55 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to a nonelected invention.
3. Claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44 45, and 47-49 are under consideration.

### **Rejections Withdrawn**

4. The rejection of claims 8, 10, 11, 13, 14, 16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the claim amendments.

### **Rejections Maintained**

5. The rejection of claim 7, 8, 10, 11, 15, 16, 18, and 19 under 35 U.S.C. 103(a) as being unpatentable over Lowrie et al (*Vaccine*, 15(8):834-838, 1997) is maintained.

Applicants argue that Lowrie et al do not teach or suggest the claimed invention as newly amended, i.e., a vaccine that contains a vector containing a polynucleotide that has a plurality of *M. tuberculosis*.

The examiner has considered applicants' arguments, but does not find them persuasive. Lowrie et al does teach that mice were immunized by injections of plasmid DNA (Figure 2, legend, page 836), and the statement on page 837 both suggests and provides the motivation for a method of eliciting immune responses in a subject by injecting a polynucleotide comprising multiple antigen encoding sequences.

Art Unit: 1645

6. The rejection of claims 23, 25-30, 32, 33, 37-42, 44, and 45 under 35 U.S.C. 103(a) as being unpatentable over Lowrie et al (*Vaccine*, 15(8):834-838, 1997) in view of Sanford et al (U.S. Pat. No. 5,100,792) is maintained.

Applicants argue that Lowrie et al do not teach or suggest the claimed invention as newly amended, i.e., a vaccine that contains a vector containing a polynucleotide that has a plurality of *M. tuberculosis*.

The examiner has considered applicants' arguments, but does not find them persuasive. Lowrie et al does teach that mice were immunized by injections of plasmid DNA (Figure 2, legend, page 836), and the statement on page 837 both suggests and provides the motivation for a method of eliciting immune responses in a subject by injecting a polynucleotide comprising multiple antigen encoding sequences.

#### **New objection necessitated by Amendment**

7. Claims 13, 14, 22, 24, 35, and 36 are objected to as being dependent from rejected claims.

#### **Conclusion**

8. Claims 7, 8, 10, 11, 15, 16, 18, 19, 21, 23, 25-30, 32, 33, 37-42, 44, 45, and 47-49 are finally rejected.

9. Claims 13, 14, 22, 24, 35, and 36 are objected to as being dependent from rejected claims.

10. Applicant's amendment necessitated the new grounds of objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1645

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

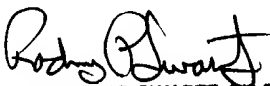
If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit 1645

August 9, 2004

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER